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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,146	01/02/2001	Rolando Barbucci	515-4204	8284

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NEW YORK, NY 10036

EXAMINER
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SERGEANT, RABON A

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/622,146	BARBUCCI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rabon Sergeant	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5-21 and 24-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-21 and 24-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1711

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1, 9-13, 17-20, 26-30, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Shah et al. ('032).

Patentees disclose coating compositions comprising blocked polyisocyanates and hyaluronic acid derivatives, wherein the hyaluronic acid derivatives may be sulfated hyaluronic

Art Unit: 1711

acid. Patentees further disclose that the coatings may contain drugs and may be applied to plastics, including polyurethanes, and medical articles. See abstract; column 3, lines 5-11 and 50+; and column 4, lines 13-15. The position is taken that upon curing, a compound results that meets applicants' claimed covalently bound polyurethane-hyaluronic acid derivative compound, especially when the coating is cured upon the disclosed polyurethane substrate. Furthermore, the disclosure of sulfated hyaluronic acid is considered to encompass applicants' claimed O-sulphated hyaluronic acid derivative. This position is logical in view of the fact that sulfated hyaluronic acid is considered to refer only to N-sulphated and O-sulphated species.

3. Claims 2, 6, 8, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. ('032).

As aforementioned, patentees disclose coating compositions comprising blocked hexamethylene diisocyanate and hyaluronic acid derivatives, wherein the hyaluronic acid derivatives may be sulfated hyaluronic acid. Patentees further disclose that the coatings may be applied to plastics, including polyurethanes. See abstract; column 3, lines 5-11 and 50+; and column 4, lines 13-17. The position is taken that upon curing, a compound results that is analogous to applicants' claimed covalently bound polyurethane-hyaluronic acid derivative structure, especially when the coating is cured upon the disclosed polyurethane substrate. Though the reference is silent regarding the use of methylene bis(phenylisocyanate) as the reactant for the polyurethane substrate polymers, the position is taken that it would have been obvious to utilize this polyisocyanate in the production of virtually any polyurethane given its commercial availability and prevalence within the polyurethane polymer field. Polyurethane derived from this polyisocyanate, when used as the polyurethane substrate polymer would have

Art Unit: 1711

yielded applicants' claimed structure of claims 6, 8, and 25. Furthermore, the disclosure of sulfated hyaluronic acid is considered to encompass applicants' claimed O-sulphated hyaluronic acid derivative. This position is logical in view of the fact that sulfated hyaluronic acid is considered to refer only to N-sulphated and O-sulphated species.

4. Claims 1, 9, 10, 13, 17-20, 26, 27, 30, and 34 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/45335.

The reference discloses the covalent bonding of O-sulphated hyaluronic acid to a polyurethane cardiac valve. See page 11, lines 15+ and Example 8 within WO 98/45335. The position is taken that the process of Example 8 forms a film on the cardiac valve that meets applicants' claimed compound. As evidence that the hyaluronic acid is covalently bonded to the polyurethane, applicants' attention is directed to Process B, as disclosed within page 16 of WO 96/24392. Process B parallels Example 8 of WO 98/45335, and it is disclosed that such a process bonds hyaluronic acid to the substrate.

5. Claims 1, 2, 5, 9-21, 24, and 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/45335.

As aforementioned, the reference discloses the covalent bonding of O-sulphated hyaluronic acid to a polyurethane cardiac valve. See page 11, lines 15+ and Example 8 within WO 98/45335. The reference further discloses that the hyaluronic acid component may be in the form of applicants' claimed partial esters and is compatible with drugs and natural, semi-synthetic, and synthetic polymers. See pages 6 and 8-10. Therefore, the position is taken that it would have been *prima facie* obvious to utilize these disclosed modified esters of hyaluronic acid

Art Unit: 1711

and/or compatible drugs and/or polymers in accordance with the teachings of Example 8, so as to arrive at the instant invention.

6. Applicant cannot rely upon the foreign priority papers to overcome these rejections because a translation of said papers has not been made of record in accordance with 37 CFR

1.55. See MPEP § 201.15.

7. Applicants' arguments with respect to Shah et al. and WO 98/45335 have been considered; however, despite applicants' response, applicants have not distinguished the instantly claimed compound from the teachings of Shah et al or WO 98/45335. It is not seen that applicants' claims require any form of isolation of the argued compound and one would be hard pressed to argue that the reaction product disclosed by the references does not comprise a compound, to the extent claimed. Furthermore, in response to applicants' arguments concerning priority, a translation of the priority papers has not been made of record in accordance with 37 CFR 1.55. Furthermore, with respect to Shah et al., despite applicants' arguments, Shah et al. do in fact teach that a solvent is present within the composition and that its removal is merely preferred and therefore optional. See column 3, lines 12-14. Given the disclosed presence of the solvent, applicants have not established that the argued reactions do not occur in the presence of the solvent. Lastly, applicants' arguments concerning improved properties have been considered; however, it is not seen that applicants have set forth comparative examples that are representative of the relied upon prior art.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balazs et al. ('865) in view of WO 95/25751 and Halpern et al. ('114).

Art Unit: 1711

Balazs et al. disclose the covalent bonding of hyaluronic acid to polyurethane and the use of such materials in medical applications. See example 3.

9. Balazs et al. are silent regarding the sulphate modification of the hyaluronic acid component; however, sulphated hyaluronic acids and their use with polyurethanes and within medical applications was known in the art at the time of invention. This position is supported by the teachings of WO 95/25751. See entire document and especially line 20 of page 28.

Furthermore, the covalent bonding of polysaccharides, including sulphate containing polysaccharides, to substrates, including isocyanate group containing substrates, to produce medical articles was known at the time of invention. See abstract; figures; and column 4, lines 20+ within Halpern et al.

10. In view of the teachings within Halpern et al. regarding the bonding of sulphate polysaccharides to isocyanate containing substrates, the position is taken that it would have been obvious to utilize the sulphated hyaluronic acids of WO 95/25751 as the hyaluronic acid component of Balazs et al., so as to arrive at the instant invention.

11. The prior art rejection of claim 7 in view of Balazs et al. ('865) and further in view of WO 95/25751 and Halpern et al. ('114) has been reinstated, because, by applicants' amendment, claim 7 is no longer limited to O-sulphated hyaluronic acid derivatives. Accordingly, the claim is no longer commensurate in scope with applicants' previous arguments or the previously presented 37 CFR 1.132 declaration.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1711

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to R. Sergent at telephone number (571) 272-1079.

R. Sergent  
August 20, 2006

  
**RABON SERGENT**  
**PRIMARY EXAMINER**